

K061824 (Pg 1 of 2)
TORNIER
Implants Chirurgicaux

Summary of Safety and Effectiveness information
510(k) Premarket Notification – Tornier Cement restrictor

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: *Tornier Cement Restrictor*
Common name: Cement Restrictor
Classification name: Surgical mesh

SEP 14 2006

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Mireille Lémery
Regulatory affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: 00 33 4 76 61 38 98
Fax: 00 33 4 76 61 35 33
e-mail : mireille.lemery@tornier.fr

4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: LZN

5) Equivalent / Predicate device

Tornier Cement Restrictor, TORNIER, K973453, K001932
Allo Pro Cement Obturator, ALLO PRO, GmbH, K830949
Allen Medullary Cement Plug, ZIMMER, Inc, K001733

6) Device description

The Tornier Cement Restrictor is a diaphyseal plug for orthopedic use. It is designed to occlude the medullary cavity before the introduction of acrylic cement. The Tornier Cement Restrictor is used to prevent the cement progression in the diaphysis and therefore facilitate the cement pressurization during the introduction of the implant. Its flexible mechanism makes it adaptable to different diameters of medullary canal to be occluded.

Page 1/ page 2



TORNIER S.A.S.
161, rue Lavoisier - Montbonnot
38334 SAINT-ISMIER CEDEX
FRANCE

Tél. : 33 (0)4 76 61 35 00
Fax : 33 (0)4 76 61 35 33

S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

K061824 (pg 2 of 2)

TORNIER

Implants Chirurgicaux

The present device modification submission consists in the addition of a small diaphyseal plug and an extension of the indication for use.

7) Materials

The Tornier cement restrictor is made of ultra high molecular weight polyethylene according to ISO standard 5834-2. The radiographic marker is made of stainless steel according to ISO standard 5832-1.

8) Indications

The Tornier Cement restrictor is a diaphyseal plug designed to occlude the medullary cavity before the introduction of acrylic cement during joint arthroplasty. The Tornier Cement restrictor prevents the cement from flowing down the diaphysis and therefore facilitates cement pressurisation when the implant is introduced.



TORNIER S.A.S.
161, rue Lavoisier - Montbonnot
38334 SAINT-ISMIER CEDEX
FRANCE

Tél. : 33 (0)4 76 61 35 00
Fax : 33 (0)4 76 61 35 33

S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tornier
% Mrs. Mireille Lemery
161, rue Lavoisier – Montbonnot
38334 Saint Ismier Cedex -France

SEP 14 2006

Re: K061824
Trade/Device Name: Tornier Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: LZN
Dated: June 13, 2006
Received: June 29, 2006

Dear Mrs. Lemery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mrs. Mireille Lemery

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061824

Device Name: Tornier Cement Restrictor

Indications For Use:

The Tornier Cement restrictor is a diaphyseal plug designed to occlude the medullary cavity before the introduction of acrylic cement during joint arthroplasty. The Tornier Cement restrictor prevents the cement from flowing down the diaphysis and therefore facilitates cement pressurisation when the implant is introduced.

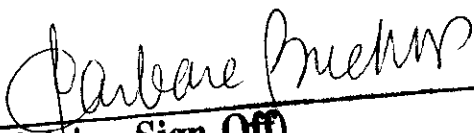
Prescription Use ☒ X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K061824